

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In Re Application of: Dov HARTAL et al

Application No.: 09/449,093

Filed: November 224, 1999

For: NATURAL COLORING PRODUCTS

Art Unit: 1761

Examiner: C.E. SHERRER

Arlington, VA

Atty.'s Docket: HARTAL=1B

Date: April 15, 2005

Confirmation No.: 5856

Randolph Building, Customer Window, Mail Stop Appeal Brief - Patents
U.S. Patent and Trademark Office
401 Dulany Street
Alexandria, VA 22314

Sir:

Transmitted herewith is a [X] REPLY UNDER 37 CFR 41.41 in the above-identified application.

[] Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted

[] A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.

[] Fee for Filing a Brief in Support of an Appeal ____

The fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA EQUALS
TOTAL	* 25	MINUS	** 20	0
INDEP.	*	MINUS	*** 3	0
FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				

SMALL ENTITY	
RATE	ADDITIONAL FEE
x 9	\$
x 43	\$
+ 145	\$
ADDITIONAL FEE TOTAL	
\$	

OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE
x 18	\$
x 86	\$
+ 290	\$
TOTAL	
\$	

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 20, write "20" in this space.

*** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 3, write "3" in this space.

[] The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment of the number of claims originally filed.

[XX] Conditional Petition for Extension of Time

If any extension of time for a response is required, applicant requests that this be considered a petition therefor.

[] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity

Response Filed Within

[] First - \$ 55.00
[] Second - \$ 210.00
[] Third - \$ 475.00
[] Fourth - \$ 740.00

Month After Time Period Set

Other Than Small Entity

Response Filed Within

[] First - \$ 110.00
[] Second - \$ 420.00
[] Third - \$ 950.00
[] Fourth - \$ 1480.00

Month After Time Period Set

[] Less fees (\$) already paid for month(s) extension of time on .

[] Credit Card Payment Form, PTO-2038, is attached, authorizing payment in the amount of \$.

[XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR §1.16 and all patent processing fees under 37 CFR §1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR §1.18.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:) Art Unit: 1761
)
Dov Hartal et al) Examiner: C.E. Sherrer
)
Appln. No.: 09/449,093) Washington, D.C.
)
Date Filed: November 24, 1999) April 15, 2005
)
For: NATURAL COLORING PRODUCTS) Confirmation No.: 5856
)
) ATTY.'S DOCKET: HARTAL=1B

REPLY BRIEF UNDER 37 CFR 41.41

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window
Randolph Building, Mail Stop APPEAL BRIEF-PATENT
401 Dulany Street
Alexandria, VA 22314

Sir:

This is a Reply Brief on behalf of Appellants, filed under 37 CFR 41.41 in reply to the Examiner's Answer mailed February 15, 2005, approximately 13.5 months after Appellants' Brief filed December 29, 2003.

I. The examiner states under heading "(5) Summary of Invention" at pages 2 and 3 of the Examiner's Answer, that Appellants' "Summary of Invention" section is "somewhat misleading". Appellants believe that it is accurate, and thus address the following points raised by the Examiner.

I.A. Page 1, fourth paragraph of Appellants' specification does indeed refer to "natural colors", of which lycopene is one. The same paragraph of Appellants' specification refers to beta-carotene as one of these colors from natural sources, and the fifth paragraph of page 1 of Appellants' specification explicitly states that lycopene is "like beta-carotene", and "belongs to the family of carotenoids."

Appellants believe that their specification is clear to the effect, as stated in Appellants' main Brief, that "heating is therefore disadvantageous, and the problem with conventionally extracted lycopene is that its exposure to oxygen, particularly under the effects of even only moderate heat cause lycopene to lose its bright red color." One skilled in the art, reading Appellants' specification, would certainly understand Appellants' quoted statement as being consistent with Appellants' specification, especially considered in its entirety.

For example, the second sentence in the top paragraph on page 2 of Appellants' specification points out that "conventional methods of extraction [which employ

substantial heat¹] destroy the crystalline structure of [the lycopene] pigment, thus altering its red color to orange-yellow,...." (bracketed material added).

I.B. In the bottom paragraph on page 2 of the Examiner's Answer, the Examiner quotes from Appellants' specification, page 7, first paragraph, only part of the sentence in question. Such sentence in its entirety reads as follows:

Additionally, the chromoplast particles containing crystalline lycopene, separated from the fruit which contain them, have been found to be relatively insensitive to the effects of heat and oxidation, which strongly and adversely effect pure lycopene.

This sentence accurately states that the chromoplast shells or capsules protect the crystalline lycopene, and it is of course an object of the invention to preserve the chromoplast as much as possible.

As regards the wording "relatively insensitive to the effects of heat and oxidation", the Examiner apparently misunderstands what this means. It means "relatively" to the unprotected lycopene, i.e. the lycopene which has been freed from the chromoplast shells. It does not mean that

¹ See, for example, the Hartal Declaration of record, page 2, where Dr. Hartal states as fact: "Conventional processing inevitably uses elevated temperatures and equipment that causes mechanical damage to the chromoplasts and results in the oxidation of large portions of the exposed lycopene."

the chromoplast particles are insensitive to the effects of heat, only that they are "relatively insensitive to the effects of heat" compared with lycopene which has been freed from the protective chromoplast shells.

I.C. Next, the Examiner states (sentence spanning pages 2 and 3 of Examiner's Answer) that "appellants state that the instant product can be pasteurized", but the Examiner does not indicate where he sees this language. Presumably, however, the Examiner is referring to the last sentence on page 10 of Appellants' specification.

First, pasteurization can be carried out without the use of heat, e.g. using gamma radiation. However, if pasteurization is attempted using heat, and the degree of heat is such as to substantially disrupt the chromoplasts and oxidize the lycopene crystals released from the chromoplasts, then obviously that degree of heat cannot be used, and this should be clear to anyone reading Appellants' specification.

I.D. Appellants' specification states at the top of page 5 that processes of making conventional tomato products cause destruction of the chromoplast membrane, and the Examiner complains that there "is no citation for this statement, nor was one found." But this is clear from

Appellants' specification as a whole, including the statement from top of page 7, last sentence in the quote appearing on page 5 of Appellants' main Brief, i.e. the crystalline structure of lycopene... is not destroyed or otherwise changed [in the present invention], as occurs with **rigorous extraction** of the chromoplasts." (emphasis added) Heating of the type conventionally carried out in the prior art involves "rigorous extraction" and consequent disruption or destruction of the chromoplasts. This is fully consistent with what is stated above in part I.A. with reference to the quote from the fourth paragraph of page 1 of Appellants' specification which indicates destruction by heat.

This is also confirmed by Dr. Hartal's Declaration, noting for example part 1 at page 2:

In production of the coloring material according to our invention, we employ mild, i.e. gentle, conditions that assure minimal damage to the protective chromoplasts and to the lycopene in them. We avoid high temperatures and prolonged heating and exposure to air.

And paragraph 4 of Dr. Hartal's Declaration further indicates that the type of heating prevalent in the prior art "will inevitably destroy all or substantially all of the chromoplasts, and accelerate the oxidation of lycopene,

whereby the results of the present invention are impossible."

Paragraph 7(d) at page 5 of Dr. Hartal's Declaration indicates that the heating in Bradley, which states that the chopped tomatoes "are heated to inactivate enzymes" (quote from Bradley), "will inevitable destroy chromoplasts" (quote from paragraph 7(d) of Dr. Hartal's Declaration). Also please see paragraphs 7(e) and (f) of Dr. Hartal's Declaration which further support Appellants' statement that the processes of making conventional tomato products causes destruction of the chromoplast membrane.

I.E. Next, the Examiner criticizes Appellants' "Summary of the Invention" statement at the bottom of page 5 of Appellants' main Brief to the effect that "a key aspect of the present invention... is to liberate the chromoplast from the fruit without causing substantial mechanical breakage... of the chromoplast particle." Appellants believe that it is very clear from Appellants' specification that this is indeed a key feature of the present invention. For example, reference is made to the top paragraph on page 7 of Appellants' specification which is quoted on page 5 of Appellants' main Brief, immediately above the criticized sentence.

Further in this regard, the second paragraph on page 7 of Appellants' specification emphasizes this point, stating as follows:

It is an aspect of the invention, therefore, to use as color-imparting agent lycopene, containing or comprising chromoplasts separated from the fruit which contained or comprised them.

Thus, the present invention involves producing a red coloring agent which comprises not only lycopene crystals, but lycopene crystals within and protected by the chromoplast shells.

I.F. Lastly, the Examiner expresses being baffled by "why, if the chromoplast particles (some being broken) are so inherently insensitive to heat and oxidation, the lycopene crystals are destroyed in the prior art processes (that apparently utilize heat and oxidation), when said lycopene crystals are protected within the chromoplast particles." As is made clear Appellants' specification and confirmed by Dr. Hartal's Declaration, and as already pointed out above and in Appellants' main Brief, the harsh treatments of the prior art (including excessive heat and rough mechanical treatments) tend to rupture and destroy the chromoplast shells, thus exposing the lycopene crystals which are highly sensitive to oxidation from the heat applied.

According to the method of the present invention, damaging heat is avoided thereby maintaining the lycopene within the protective chromoplast shells where it cannot be easily oxidized, thus retaining the rich red color desired. The chromoplast protected lycopene is then easily washed free of components which provide the taste and aroma of the fruit (usually tomatoes) so the resultant red coloring material can be used to color food products where a tomato taste would be undesirable. Thus, as stated at the beginning at the bottom paragraph on page 9 of Appellants' specification:

In many cases, specifically when the food product to be colored is not related to the source of the coloring material, natural flavors found therein render it unsuitable for use. For instance, when coloring a sweet fruit desert, even a small level of tomato flavor is highly undesirable. Since the color imparting agents of the invention are solid water-insoluble materials, rinsing removes only the water soluble flavor components..., while the color value remains constant.

And from the middle paragraph on page 8 of Appellants' specification:

..., nowhere in the art can be found a teaching that chromoplast particles containing a crystalline carotenoid, such as lycopene, can be directly used as a color imparting agent, ..., nor that such material will retain a higher coloring power and a deeper red shade.

Also please see the first three paragraphs on page 5 of Appellants' specification in this regard.

II. As regards the rejection based on the "Description of the Invention" requirement of the first paragraph of §112, Appellants' believe that their main Brief at pages 13 and 14 is adequate, and nothing further is needed. Appellants merely wish to again state, as stated above (see Part I above), that it is clear from Appellants' specification to anyone skilled in the art, i.e. those to whom the present specification is directed, that the claimed coloring material comprises from 500 to 3,000 ppm of the chromoplast particles encapsulating crystalline lycopene, as claimed.

III. As regards the rejection based on lack of enablement under the first paragraph of §112, the Examiner mistakenly accuses Appellants of not disclosing critical features of the present invention. Appellants rely on their main Brief commencing at the bottom of page 14 and extending to near the bottom of page 17. As pointed out in Appellants' specification, Appellants separate the chromoplasts by the use of gentle centrifugal force. See the examples.

Appellants' specification is directed to those skilled in the art. However, even those of skill less than those skilled in the present art would be able to extract substantially intact chromoplasts based on Appellants' disclosure that it is desirable to do so. Certainly those skilled in the art, without any experimentation at all, or at most only routine experimentation, could easily produce Appellants' product. Appellants' invention is well enabled by Appellants' specification.

IV. The Examiner has clarified his rejection based on the second paragraph of §112, and it is now limited to only to claim 5.

The Examiner insists that "high lycopene content tomato" is indefinite, actually "unknown". Appellants see absolutely no basis for the Examiner's position. Attention is respectfully invited, for example, to page 9 of Appellants' specification, line 5, which indicates that a starting material can be "a tomato variety which is especially rich in lycopene". Paragraph 7 at the top of page 4 of Dr. Hartal's Declaration explicitly states that high lycopene content tomatoes are well known.

The Examiner raises a red herring by saying that Appellants may not rely on the Hartal Declaration because one "cannot introduce new information into the record unless

it relies on a disclosure predating the application date." As pointed out above and in Appellants' main Brief, Appellants' specification already states that one can use a tomato variety which is especially rich in lycopene, i.e. a high lycopene content tomato, meaning that those tomatoes were already available at the time the present application was filed. Dr. Hartal's Declaration merely confirms such a fact and thus collaborates what is already in Appellants' specification.

There is simply no basis for the Examiner's position.

V. The Examiner's reliance on Graves under §102 is believe by Appellants to be, respectfully, bottom-barrel scrapping. The Examiner suggests that it is proper to ignore what Graves states and to assume that Graves produces Appellants' product on the basis of alleged inherency, contrary to what Graves itself states. Appellants rely on their main Brief at pages 20-25.

Insofar as alleged inherency is concerned, Appellants respectfully rely on the well established case law, including that case law cited in footnote 8 at the bottom of page 34 of Appellants' main Brief. There are more recent cases to the same effect, including *Schering Corp V. Geneva Pharmaceuticals*, 67 USPQ2d 1664 (Fed Cir 2003) where

the Court stated that for inherency to exist, the missing characteristic needed to be "necessarily present".

Appellants also note *Crown Operations International v. Solutian Inc.*, 62 USPQ2d 1917, 1923 (Fed Cir 2002), where the Court stated:

Inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." (citations omitted)

Appellants believe that the legal principle could not be stated more clearly. Not only is there no certainty in Graves that Appellants' results are achieved by Graves, but the opposite is very clear in view of the statements in Graves which the Examiner chooses to ignore or brush aside.

VI. At the bottom of page 15 of the Examiner's Answer, the Examiner brushes aside the Hartal Declaration because "it provides no data..." Respectfully, the Examiner commits error when he chooses to ignore evidence, and the Hartal Declaration is indeed evidence. It contains factual statements which must be accepted as fact in the absence of evidence or good reasoning to the contrary, neither of which have been presented.

To the extent that Dr. Hartal also provides his opinions, they also are evidence as "expert opinion", in view of the fact that Dr. Hartal is indeed an expert in the

present art. There is no justification for the Examiner to brush aside Dr. Hartal's Declaration on the simple basis that "is not found persuasive."

Appellants respectfully note the words of Judge Rich, speaking for the Court in *In re Khelghatian*, 150 USPQ 661, 663, footnote 2 (CCPA 1966), commenting on the decisions of the Supreme Court in *Graham v. John Deere Co.*, 383 US 1, 148 USPQ 459, and *United States v. Adams*, 383 US 39, 148 USPQ 479:

In our view the Court there said nothing at all about 'doubtful cases,' nor in any way suggested that any record evidence should not be accorded its full probative weight.... Such an approach [brushing off a Declaration because the examiner "is satisfied" that the invention is unpatentable] is reminiscent of the proverbial "don't bother me with the facts, my mind is made up" method of decision and has, we think, no place in the application of 35 U.S.C. 103. We therefore remain of the view that the law requires consideration of all **evidence**, properly submitted...." (emphasis in original; bracketed material added)

Appellants respectfully repeat that Dr. Hartal's Declaration is evidence and may not properly be brushed aside as the Examiner has done.

VII. In the same paragraph in which the Examiner brushes aside Dr. Hartal's Declaration, the Examiner incorrectly states that the burden is on Appellants. This

is not so. The burden is on the Examiner to establish both anticipation and obviousness. The Examiner has not done so.

VIII. As regards the rejection based on Tonnuci, Appellants continue to rely on their main Brief, as Appellants do with respect to all of the rejections.

Appellants simply do not understand the Examiner's comment that claim 14 is not limited to any Brix value. Claim 14 clearly recites a tomato product colored with the material according to claim 1. As pointed out in Appellants' main Brief on page 26, this requires two things, namely (1) a tomato product, and (2) a coloring agent, and the coloring agent is what is recited in claim 1. Tonnuci contains not the remotest hint of such a combination.

IX. As regards the rejection based on Brumlick, the Examiner again appears to rely on what the Examiner **thinks** that Brumlick **inherently** produces. But as with the other prior art, it is clear that not only is there no **certainty** that Brumlick produces Appellants' product, but from what is stated in Brumlick as pointed out in Appellants' main Brief at pages 27-28, Brumlick clearly does not provide what Appellants' claim.

The Examiner has not met his burden.

X. As regards the anticipation rejection based on Szabo, again Appellants rely on their main Brief at pages 29 and 30, and what is stated in Szabo. It cannot be doubted that Szabo discloses and teaches **evaporation**, and that at least implies or suggests the use of substantial heat. Regardless, it cannot be validly said, as the Examiner's posits, the Szabo **inherently** produces Appellants' claimed product. Again, there is absolutely no certainty; and, in the absence of certainty, there is no inherency and no anticipation.

As with the other rejections, the Examiner has not met his burden.

XI. In the first full paragraph on page 17 of the Examiner's answer, and in connection with the anticipation rejection based on Szabo, the Examiner states that "Appellants do not claim this attribute", i.e. that in the present invention, the tomato smell and taste are largely eliminated. But Appellants need not claim such subject matter, as it is an attribute or characteristic of Appellants' product, and thus part of Appellants' product whether or not such attribute is claimed². The fact that Appellants' claims recite the chromoplast particles

² This is the same as claiming a new compound. When naming the compound, one is claiming the compound, not the name, and that includes whatever characteristics that compound has.

encapsulating crystalline lycopene, with the chromoplast particles being "separated from a fruit which contained them", means that the tomato smell and taste are eliminated as pointed out in Appellants' specification as noted above.

XII. As with the other prior art rejections, the Examiner seeks to ignore what Bradley actually states, i.e. that the heating is carried out "to inactivate enzymes". Based on his expertise, Dr. Hartal has stated that when heating is done as in Bradley, i.e. "to inactivate enzymes", this will [paragraph 7(d) of Dr. Hartal's Declaration] "inevitably destroy chromoplast." Again, the Examiner has not met his burden.

XIII. As regards the anticipation rejection based on Lang, Appellants continue to rely on their main Brief at pages 33-35. Again, the Examiner prefers to ignore what the reference states, it being again noted that Lang heats sufficiently to denature the polygalactonase in the tomatoes. Dr. Hartal states in his Declaration that heating according to Lang to deactivate the pectolytic enzymes in the tomatoes "will result in the destruction of the chromoplasts". As with the other applied references, it cannot be validly said that Lang will inherently produce what is claimed because there is no certainty that Lang will

do so, and indeed Dr. Hartal's experience has caused him to conclude the opposite.

XIV. As regards the documentary evidence, and particularly the Examiner's comment at the bottom of page 17 of the Examiner's Answer regarding the "White Book...", Appellants have never taken the position that heat will destroy all the lycopene. Please note page 2 above, second paragraph, where it is pointed out that Appellants have stated that heat will cause break down of the lycopene crystalline structure causing oxidation and loss of "bright red color", not that the lycopene will be destroyed.

At the bottom of page 15 of the "White Book", the following text appears:

From these first studies, it was concluded that lycopene is quite sensitive to heat treatments in the presence of oxygen.

This is what is stated by those skilled in the art. How this is contrary to Appellants' position, as the Examiner seems to suggest, is unclear to Appellants.

XV. The Examiner has basically added nothing regarding the rejections based on §103. Accordingly, Appellants need add nothing further than what is already stated in Appellants' main Brief.


XVI. Appellants again respectfully maintain that the Examiner has not met his burden. The prior art rejections are far-fetched, and Appellants' specification is directed to those persons skilled in the art who would certainly be able to make and use Appellants' invention after having been told (per Appellants' specification) that the objective is to prevent rupture of the chromoplasts to the greatest extent possible, using gentle separation techniques.

Appellants again respectfully request reversal of the rejections of record.

Respectfully submitted,

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